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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,965	11/14/2003	Charles H. Pugsley	06530.0288-01	7789

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
THAI, VANESSA K	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,965	PUGSLEY ET AL.	
	Examiner	Art Unit	
	Vanessa K. Thai	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *25-36* is/are allowed.

6)☒ Claim(s) *1-4 and 7-24* is/are rejected.

7)☒ Claim(s) *5 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/08/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a first Office action on the merits of 10/706,965.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on November 8, 2004 is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3. In the instant application, each letter in the section heading should appear in upper case, without underlining or bold type.

4. The disclosure is objected to because of the following informalities:

- On p. 22, paragraph 71, line 13, the word "generically" should be "genetically".

Appropriate correction is required.

Claim Objections

5. Claims 11, 15, and 24 are objected to because of the following informalities:

- In claim 11, line 2, the word "the" should be deleted from the sentence "to be peeled away from (the) at least one of the substrate..."
- In claim 15, line 3, the word "generically" should be "genetically".
- In claim 24, line 1, the word "to" is missing from the sentence "the carrier is configured (to) be..."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1 – 4, 7 – 16, and 18 – 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Binette et al. ('428).

Binette et al. disclose in Figure 3, a tissue patch (10) comprising a substrate (12), a tissue implant (11) attached to the substrate (12), and a protective liner (16) covering at least a portion of the tissue implant (11); wherein the tissue implant (11) is placed on a surface of the substrate (12); wherein the tissue implant (11) is embedded in the substrate (12) in the form of a cellular suspension (col. 2, lines 57 – 58); wherein the substrate (12) has a first surface (14) for receiving the tissue implant (11) and a second surface (20) opposite to the first surface (14) for facing the lumen of the alimentary tract; wherein an adhesive material holds the patch proximate the lesion (col. 17, lines 18 – 23); wherein the adhesive material includes cyanoacrylate (col. 17, lines 24 – 25); wherein the protective liner (16) is attached to the substrate (12) via an adhesive material (col. 16, lines 40 – 44); wherein the protective liner (16) is removably attached to at least one of the substrate (12) and the tissue implant (11); wherein the protective liner (16) is configured to be peeled away from at least one of the substrate (12) and the tissue implant (11); wherein the protective liner (16) is removably attached to the substrate (12); wherein the substrate (12) is a bio-absorbable gel (col. 3, lines 65 – 66); wherein the substrate (12) includes bio-absorbable material having a predetermined thickness designed to last for a predetermined time period required for healing of the lesion so as to protect the tissue implant (11) from conditions in the

alimentary tract (col. 7, lines 10 – 11); wherein the substrate (12) includes a therapeutic agent, such as antibiotics (col. 8, lines 44 – 45; lines 50 – 52); wherein the patch (10) is configured to be delivered endoluminally; wherein the patch (10) is configured to be folded into a contracted state during delivery into the lesion; wherein the patch (10) is capable of expanding upon deployment into the lesion; and wherein the patch (10) is configured to be rolled into a cylindrical shape.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 17 and 22 – 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binette et al. in view of Naimark et al. ('431).

Binette et al. disclose the invention substantially as claimed in claims 1 – 4, 7 – 16, and 18 – 21, except for a therapeutic agent that is layered in a predetermined depth within the substrate so that the therapeutic agent activates at a predetermined time; wherein the tissue implant is a genetically engineered tissue; wherein a carrier is attached to the substrate; and wherein the carrier is configured to be peeled away from the substrate.

However, Naimark et al. disclose a therapeutic agent that is layered in a predetermined depth within the substrate so that the therapeutic agent activates at a predetermined time (col. 16, lines 60 – 66); wherein the tissue implant is a genetically

engineered tissue (col. 14, lines 40 – 46); wherein a carrier is attached to the substrate (col. 15, lines 52 – 53); and wherein the carrier is configured to be peeled away from the substrate (col. 15, lines 27 – 28).

Binette et al. and Naimark et al. are analogous art because they are from the same field of endeavor. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the tissue patch of Binette et al., in view of Naimark et al., to include a therapeutic agent that is layered in a predetermined depth within the substrate so that the therapeutic agent activates at a predetermined time for the purpose of controlling the rate of delivering the therapeutic agent to the body tissue; to include a tissue implant that is genetically engineered for the purpose of delivering proteins of interest to the target site; to include a carrier that is attached to the substrate for the purpose of holding the tissue implant; and to include a carrier that is configured to be peeled away from the substrate for the purpose of revealing the tissue implant to the body tissue surface being treated.

Allowable Subject Matter

10. Claims 5 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter in claims 5 and 6:

- None of the prior art alone or in combination teaches a tissue patch comprising a tissue implant that occupies an area in the first surface of

a substrate, the area being less than the surface area of the first surface.

12. Claims 25 – 36 are allowed.

13. The following is a statement of reasons for the indication of allowable subject matter in claims 25 - 26:

- None of the prior art alone or in combination teaches a method of treating a lesion in a lumen of a patient's body, comprising positioning the tissue patch in the vicinity of the lesion, removing the protective liner to reveal the tissue implant, and placing the tissue implant in the lesion.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa K. Thai whose telephone number is 571-272-5530. The examiner can normally be reached on M - F 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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vkt

KEVIN T. TRUONG
PRIMARY EXAMINER